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1372549

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(19)

(54) INJECTOR DEVICE

(71) We IMS LIMITED, a corporation organised according to the laws of the State of Delaware, United States of America of 1930 Santa Anita Avenue, South El Monte, California 91733, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to injector devices, and especially to such devices when used for the addition of medicinal solutions to intravenous solution bottles.

The invention provides an injector device for the addition of medication to stoppered solution containers, the injector device comprising: a cylindrical vial having an open end and a closed end, a resilient plug for said vial which forms a sealing engagement with the walls of said vial with a press fit; a cylindrical member having one closed end and holding a needle which extends inwardly into said cylindrical member and which has a sharpened inner end; said cylindrical member having a tip extending outwardly from said closed end, said tip being an elongate member generally circular in cross-section and having a central fluid passage extending lengthwise of the tip and communicating with the interior of the needle, said tip terminating in a zone of reduced cross-section having a pointed end, said zone having at least one fluid passage which communicates with said central fluid passage and forms an oblique angle with respect thereto, and the end portion of the tip that is intended to pierce the stopper of the solution container being too large for injection into the human body; interlocking means on said cylindrical member and co-operating interlocking means on said plug; the arrangement being such that upon interlocking of said plug with said cylindrical member said vial is first held in an assembled but non-operating position and upon further interlocking of said plug with said cylindrical member, said plug is pierced by said needle and said needle communicated with said vial without the application of substantial axial pressure on said plug and said plug is locked securely to said cylindrical member to permit aspiration upon withdrawal of said vial relative to said cylindrical member and said plug or to permit expulsion of the contents of said vial into said solution container upon advancement of said vial relative to said cylindrical member and said plug.

The injector device tends to prevent coring of the stopper of the solution container. This is particularly important when the solution is intravenous solution. When the stopper is made of rubber, coring results in bits of rubber falling into the solution which can result in the injection of this dangerous blood clotting material into the patient. The pointed tip pierces the rubber rather than cutting it, the hole enlarging and stretching around the diameter of the tip in use. Thus, vacuum can be maintained in vacuum packaged solutions. The tip can be twisted or rotated without the cutting off of a rubber piece whereas such manipulation of a biased tip creates the possibility of the flap being cut off as the tip is rotated to the flap adjoinment resulting in the dropping of rubber into the solution.

The fact that the end portion of the tip is too large for injection into the human body represents a significant safety feature. Additives for intravenous solutions actually contain medication in a concentration unsuitable for direct injection into the human body. In fact, many of these additives are fatal if directly injected. This prevents (if the injector device contains such concentrated medication) the accidental injection of the concentrated medication into the body. For the same reason, the tip may have a diameter, beyond the zone, substantially greater than the diameter of a conventional injection needle to prevent accidental injection into the human body.

All of the parts present in the device can be made of readily moldable plastic and/or rubber with the exception of the vial, which vial is a simple shell vial and a conventional

needle. The device of the present invention can therefore be made on a very economical basis, and the device can be pre-loaded at a central plant, used once at the time of injection into an intravenous bottle and thereafter be disposed of. The present invention makes the application of both pre-loading and disposability possible for the addition of medicament to intravenous solution bottles. Further, the device of the invention does not require the use of roll-up metal or complicated moulded parts.

At present, intravenous solutions may or may not be supplied under vacuum. Some bottled intravenous solutions are vacuum packaged. Others are not. The intravenous solutions in flexible plastic bags are not packaged under vacuum. The present invention obviates the problem of adding medication to the intravenous solution packages since the device of this invention forces the medication into the package under positive pressure. Fluid transfer is not dependent upon a vacuum being present in the package.

Advantageously, the zone has two fluid passages forming an acute angle with respect to each other, the pointed end being positioned between said passages and being symmetrically disposed around a line running longitudinally of said central fluid passage.

Advantageously, the zone has two fluid passages, and each of said two fluid passages terminates at flat surfaces on opposite sides of said tip, the cross-section of said tip otherwise being round.

The invention also provides the combination of an injector device as defined hereinbefore, and a container of intravenous solution, said container having a stopper sealing one end thereof, and said tip being adapted to pierce said stopper to permit the contents of said vial to be transferred to said container by the exertion of pressure on said vial.

The invention will now be described in detail, by way of example, with reference to the accompanying drawings, in which:

Figure 1 shows a perspective view of one form of the device of the present invention in a disassembled state;

Figure 2 is a sectional view of the tip portion of the form of device shown in Figure 6;

Figure 3 shows, in disassembled form and sectional view, another form of device according to the invention in relationship to a typical intravenous solution bottle;

Figure 4 shows, in assembled form, the use of the device of Figure 3 for the injection of medication into an intravenous solution bottle.

Figure 5 is a perspective view of the open end of the vial and associated plug of the form of device shown in Figure 6;

Figure 6 is a sectional view of another form of device according to the invention;

Figure 7 is a side view of an alternative form of tip portion for the devices of Figures 1, 3 and 6;

Figure 8 is an enlarged view of the discharge opening in the tip of Figure 7; and

Figure 9 is a sectional view along the line 9—9 in Figure 8.

Turning to the drawings in greater detail, the injector devices of Figures 1, 3 and 6 each comprise a generally cylindrical hollow tubular holder 10 having an open end 12 and a closed end 14. Within the tubular holder 10, there is provided a thrust portion 36 (not shown in Figure 1) in the form of a cylindrical member, one end of which is open and the other end of which is closed by the closed end of the holder. The injector devices of Figures 1, 3 and 6 each have a cylindrical vial 16 having a resilient plug 18 in their open ends sealing on the inside walls of the vials 16. The plugs 18 generally, although not necessarily, have a thin imperforate central diaphragm portion. The plugs 18 are provided with an externally threaded projection 20 thereon.

The injector devices shown in Figures 1, 3 and 6 are all essentially similar in construction, like parts in the various forms of the device being like reference numerals in the drawings. The tips of the devices differ from each other in constructional details. The interior of the devices is apparent from Figures 3 and 4, to which reference is now made.

The cylindrical thrust portion 36 holds a needle 22 at its closed end, which needle extends inwardly into the thrust portion 36. The thrust portion 36 has a tip 24 extending outwardly from its closed end, which tip is provided with a fluid passage 26 extending to passages 28 and 30 in a zone of reduced cross-section, which passages are at an oblique angle to passage 26 and which terminate in openings 32 and 34. The tip 24 has a sharp pointed configuration and is adapted to puncture the stopper on an intravenous solution bottle. The fluid passages 28 and 30 form an acute angle with respect to each other, and the pointed end is positioned between the passages and is symmetrically disposed around a line running longitudinally of the central fluid passage 26. The lower end portions of the tip is too large for injection into the human body, and the diameter of the tip above the fluid passages 28 and 30 is substantially greater than that of a conventional injection needle to prevent accidental injection into the human body.

The lower end of the needle 22 communicates with a hole 38 in the closed ends of the thrust portion 36 and tubular holder 10, which in turn communicates with the fluid passage 26 of the tip 24. The upper end of needle 22 has a sharp terminal portion 40 having a hole 42 therein. The thrust portion 36 also has internal threads 44 in proximity to its upper end, the threads on the projection 20 and the threads

44 being adapted during making up to cause said sharp terminal portion 40 of the needle to puncture the plug 18. When the projection 20 is made up with threads 44, the plug 18 functions as a piston to expel the contents of the vial 16 through needle 22 and passage 26 said vial 16 is advanced into said tubular holder 10.

In operation, for intravenous use, the vial 16 containing liquid medication is partially made up with the holder 10 simply by turning the vial and the threads on projection into the threads 44. The tip 24 is then used to pierce the stopper 46 on an intravenous solution bottle 48. The threads are then further made up until the thread 20 on the plug 18 are fully made up with threads 44 as shown in Figure 4. At this point, the sharp terminal portion 40 has punctured the plug 18. By applying a slight further force on the vial, the vial can be advanced into the holder causing the plug to expel the contents of the vial through the tip as shown in Figure 4 into an intravenous solution bottle 48. The contents of the intravenous bottle is then administered to the patient in a manner familiar to those skilled in the art.

During storage, the tip 24 may be provided with a protective cover 50 (Figure 1). Such a cover is removed prior to use.

The two oblique fluid passages 28, 30 may terminate at flat surfaces on opposite sides of the tip, the cross-section of the tip being otherwise round (as in Figure 1).

All parts of the injector devices according to the invention are preferably made of plastics, save for the vials 16 and the plugs 18. The vials are normally glass vials (but may be of plastics) and the plugs may be made of a resilient rubber which is compatible with the medication contained in the vial.

The threads on the plugs may be male threads and those on the thrust portion female threads.

To fill the vials, the vials may be placed in an ordinary filling machine as commonly used by pharmaceutical manufacturers and filled with a liquid injectable. Thereafter, the plugs may be inserted in the vials 16 to the extent that all three of the sealing rings 74, 76 and 78 (Figures 5 and 6) are contained within the vial.

The threads as just described preferably engage with a loose fit so as to present substantially no frictional resistance to the making up of the threads and certainly insufficient resistance to overcome the press fit of the rings 74, 76, and 78 within the vials 16.

The needle may be secured in the holder, for example, as in Figure 6, by being cemented in a boss extending outwardly from the closed end of the holder, the boss having a bore therein, and the needle being cemented in the bore by means of an epoxy cement.

When the holder is made of plastics, the tip portion, for example, that shown in Figures 7 to 9, can be separately molded, from plastics and spun-welded to the holder. The tip is normally provided with two openings, as in Figures 7 to 9, namely, 106 and 108. However, three or even four openings are possible, and of course, a single opening can be provided where speedy discharge is not required. The edges 110 of the tip 104 are quite sharp to provide cutting surfaces. The point 112 facilitates the initial puncturing of the stopper on the intravenous solution bottle.

Attention is directed, in pursuance of Section 9 of the Patents Act, to United Kingdom Patent No. 1,159,663.

WHAT WE CLAIM IS:—

1. An injector device for the addition of medication to stoppered solution containers, the injector device comprising: a cylindrical vial having an open end and a closed end, a resilient plug for said vial which forms a sealing engagement with the walls of said vial with a press fit; a cylindrical member having one closed end and holding a needle which extends inwardly into said cylindrical member and which has a sharpened inner end; said cylindrical member having a tip extending outwardly from said closed end, said tip being an elongate member generally circular in cross-section and having a central fluid passage extending lengthwise of the tip and communicating with the interior of the needle, said tip terminating in a zone of reduced cross-section having a pointed end, said zone having at least one fluid passage which communicates with said central fluid passage and forms an oblique angle with respect thereto, and the end portion of the tip that is intended to pierce the stopper of the solution container being too large for injection into the human body; interlocking means on said cylindrical member and co-operating interlocking means on said plug, the arrangement being such that, upon interlocking of said plug with said cylindrical member said vial is first held in an assembled but non-operating position and upon further interlocking of said plug with said cylindrical member, said plug is pierced by said needle and said needle communicated with said vial without the application of substantial axial pressure on said plug and said plug is locked securely to said cylindrical member to permit aspiration upon withdrawal of said vial relative to said cylindrical member and said plug or to permit expulsion of the contents of said vial into said solution container upon advancement of said vial relative to said cylindrical member and said plug.

2. An injector device as claimed in claim 1, wherein said zone has two fluid passages forming an acute angle with respect to each other, the pointed end being positioned between said passages and being symmetrically disposed around a line running longitudinally of said central fluid passage.

3. An injector device as claimed in claim 1 or claim 2, wherein said zone has two fluid passages, and each of said two fluid passages terminates at flat surfaces on opposite sides of said tip, the cross-section of said tip otherwise being round.

4. An injector device as claimed in any one of claims 1 to 3, wherein the vial contains medication in a concentration unsuitable for direct injection into the human body.

5. An injector device as claimed in any one of claims 1 to 4, wherein the tip has a diameter, beyond the zone, substantially greater than the diameter of a conventional injection needle to prevent accidental injection into the human body.

6. An injector device substantially as hereinbefore described, with reference to, and as shown in, Figure 1 or Figures 3 and 4 or Figure 6 or Figure 6 when modified as shown in Figures 7 to 9, of the accompanying drawings.

7. The combination of an injector device as claimed in any one of claims 1 to 6, and a container of intravenous solution, said container having a stopper sealing one end thereof, and said tip being adapted to pierce said stopper to permit the contents of said vial to be transferred to said container by the exertion of pressure on said vial.

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1372549 COMPLETE SPECIFICATION
3 SHEETS This drawing is a reproduction of the Original on a reduced scale
Sheet 1

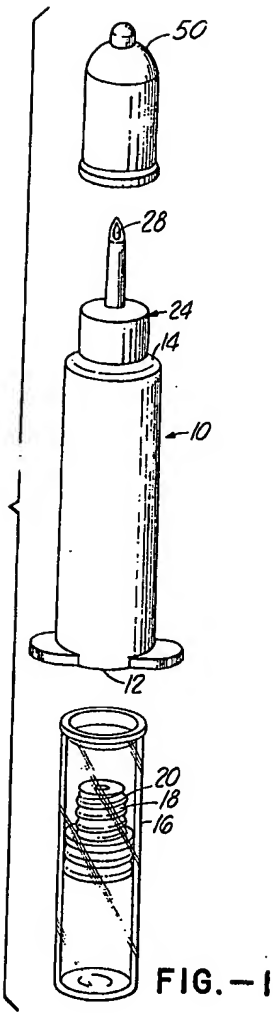

FIG.—1

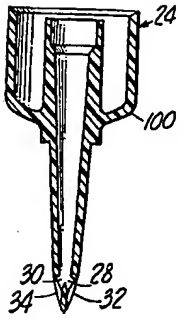

FIG.—2

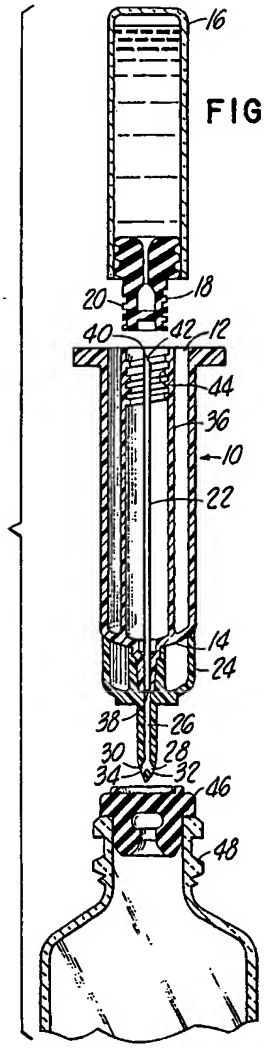
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FIG.—3

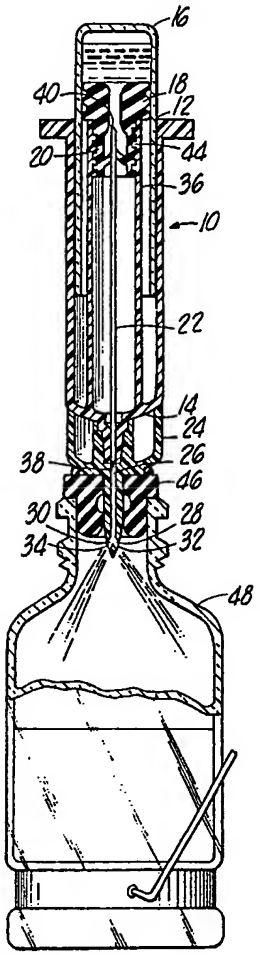
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FIG.—4

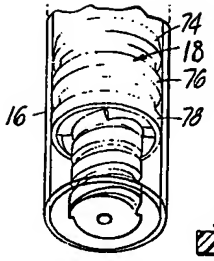

FIG.-5

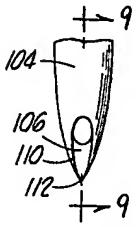

FIG.-8

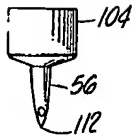

FIG.-7

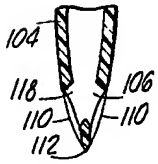

FIG.-9

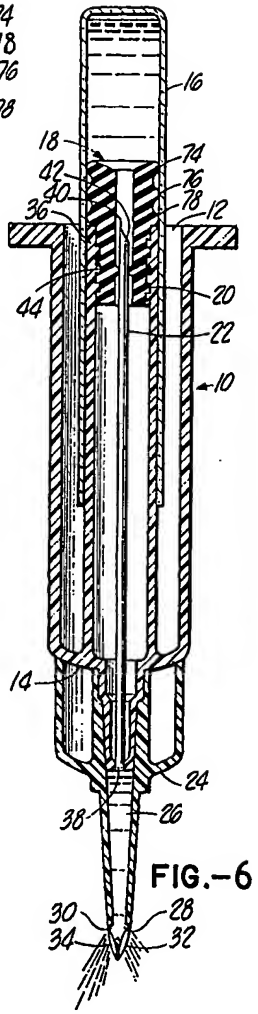

FIG.-6